



AUG 29 2005

Michael D. Alexander
Sanofi-Synthelabo Inc.
9 Great Valley Parkway
Malvern PA 19355In Re: Patent Term Extension
Application for
U.S. Patent No. 5,382,518

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,382,518, which claims the human biological product ELITEK® (rasburicase), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,638 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,638 days.

The period of extension would be 1,650 days, if calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of July 9, 2004 (69 Fed. Reg. 41509). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,420) + 940 \\ &= 1,650 \text{ days}\end{aligned}$$

Since the regulatory review period began January 27, 1996, after the patent issue date (January 17, 1995), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation, however, because it provides that the period remaining in the term of the patent, measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,650 days, would extend the patent from January 17, 2012 to July 24, 2016, which is beyond the 14-year limit (the approval date is July 12, 2002, thus the 14 year limit is July 12, 2016). The period of extension is thus limited to 1,638 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, January 17, 2012, to and including July 12, 2016, or 1,638 days.

The limitations of 35 U.S.C. § 156 (g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.: 5,382,518

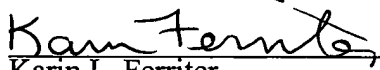
Granted: January 17, 1995

Original Expiration Date¹: January 17, 2012
Applicant: Daniel Caput, et al.
Owner of Record: Sanofi-Adventis
Title: URATE OXIDASE ACTIVITY PROTEIN,
RECOMBINANT GENE CODING THEREFOR,
EXPRESSION VECTOR, MICROORGANISMS
AND TRANSFORMED CELLS
Classification: 435/191
Product Trade Name: ELITEK® (rasburicase)
Term Extended: 1,638 days
Expiration Date: July 12, 2016

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. By FAX: (571) 272-7744
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.


Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: ELITEK® (rasburicase)
FDA Docket No. : 03E-0249

¹ Subject to the provisions of 35 U.S.C. § 41(b).